

**Summary Minutes of the Clean Air Scientific Advisory Committee (CASAC)  
Particulate Matter (PM) Review Panel Public Meeting**

**Wednesday, April 6 & Thursday, April 7, 2005**

**Marriott Durham Civic Center Hotel  
210 Foster Street, Durham North Carolina, 27701**

Panel Members: See Panel Roster – Appendix A

Dates & Times: Wednesday, April 6, 2005, 9:00 AM – 5:30 PM Eastern Time  
Thursday, April 7, 2005, 8:30 AM – 3:00 PM Eastern Time

Location: Marriott Durham Civic Center Hotel  
210 Foster Street, Durham North Carolina, 27701

Purpose: The purpose of this meeting was for the CASAC PM Review Panel to conduct a peer review of the *Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information* (second draft PM Staff Paper, January 2005); and a related draft technical support document, *Particulate Matter Health Risk Assessment for Selected Urban Areas: Second Draft Report* (second draft PM Risk Assessment, January 2005).

Attendees: Chair: Dr. Rogene Henderson

CASAC Members: Dr. Ellis Cowling  
Dr. James Crapo  
Dr. Frederick Miller  
Mr. Richard Poirot  
Dr. Frank Speizer  
Dr. Barbara Zielinska

Panel Members: Dr. Petros Koutrakis  
Dr. Allan Legge  
Dr. Paul Lioy  
Dr. Morton Lippmann  
Dr. Joe Mauderly  
Dr. Gunter Oberdorster  
Dr. Robert D. Rowe  
Dr. Jonathan Samet  
Dr. Sverre Vedal  
Mr. Ronald White  
Dr. Warren White  
Dr. George Wolff

EPA SAB Staff: Mr. Fred Butterfield, CASAC Designated Federal  
Officer (DFO)  
Dr. Vanessa Vu, SAB Staff Office Director

Other EPA Staff: John Bachmann, OAR, OAQPS  
Tim Benner, ORD, OSP  
James Brown, ORD, NCEA-RTP  
Dan Costa, ORD, OAA  
Fred Dimmick, ORD, NERL  
Barbara Driscoll, OAR, OAQPS  
Neil Frank, OAR, OAQPS  
Jay Garner, ORD [Retired], NCEA-RTP  
Lester Grant, ORD, NCEA-RTP  
Tim Hanley, OAR, OAQPS  
John Hannon, OGC, ARLO  
Brooke Hemming, ORD, NCEA-RTP  
Jeffrey Herrick, OAR, OAQPS  
Bryan Hubbell, OAR, OAQPS  
Jee Young Kim, ORD, NCEA-RTP  
Dennis Kotchmar, ORD, NCEA-RTP  
John Langstaff, OAR, OAQPS  
Karen Martin, OAR, OAQPS  
Julie McClintock, OAR, OAQPS  
Melissa McCullough, OAR, OAQPS  
David McKee, OAR, OAQPS  
Srikanth Nadadur, ORD, NHEERL-RTP  
Lucas Neas, NHEERL-RTP  
Zachary Pekar, OAR, OAQPS  
Joseph Pinto, ORD, NCEA-RTP  
Paul Reinhart, ORD, NCEA-RTP  
Harvey Richmond, OAR, OAQPS  
Mary Ross, OAR, OAQPS  
Vicki Sandiford, OAR, OAQPS  
Mark Schmidt, OAR, OAQPS  
Steve Silverman, OGC, SWERLO  
David Svendsgaard, ORD, NCEA-RTP  
Amy Vasu, OAR, OAQPS  
Tim Watkins, ORD, NERL  
Lydia Wegman, OAR, OAQPS  
Lewis Weinstock, OAR, OAQPS  
Lori White, ORD, NCEA-RTP

Other participants: Bruce Allen, ENVIRON Corp.  
Casimer Andary, Alliance of Automobile  
Manufacturers (AAM)  
Bryan Baldwin, Southern Co.  
Andrew Ballard, Bureau of National Affairs, Inc (BNA)  
Kurt Blase, O'Connor and Hannan  
Robert Connery, Holland & Hart, LLP (on behalf of  
the National Cattlemen's Beef Association)

M. Elizabeth Cox, American Petroleum Institute (API)  
Kenny Crump, ENVIRON Corp.  
Bob Hermanson, BP America  
John Graham, Northeast States for Coordinated Air  
Use Management (NESCAUM)  
Bob Hermanson, BP America  
Jon Heuss, Air Improvement Resource, Inc. (AIR)  
Philip Johnson, NESCAUM  
Martha Keating, Clean Air Task Force (CATF)  
Allen Lefohn, A.S.L. & Associates  
George Lucier, Environmental Defense  
Robert O'Keefe, Health Effects Institute (HEI)  
Ellen Post, Abt Associates  
Greg Shaefer, Arch Coal  
Katherine Shea, Physicians for Social Responsibility  
(PSR)  
Anne Smith, Charles River Associates, Inc. (CRA)  
Gina Solomon, Natural Resources Defense Council  
(NRDC)  
Joseph Suchecki, Engine Manufacturers Association  
(EMA)  
Tamara Thies, National Cattlemen's Beef Association  
(NCBA)  
Deborah Shprentz, American Lung Association (ALA)  
Allison Wood, Hunton & Williams, LLP  
Ron Wyzga, EPRI

### Meeting Summary

The discussion followed the issues and general timing as presented in the meeting agenda (Appendix B).

## **WEDNESDAY, APRIL 6, 2005**

### Convene Meeting, Call Attendance, Introduction and Administration

Mr. Fred Butterfield, Designated Federal Officer (DFO) for the CASAC, opened the meeting and the teleconference line, called attendance, and welcomed all attendees. He noted that the CASAC is a Federal advisory committee chartered under the Federal Advisory Committee Act (FACA) to provide advice and recommendations to the EPA Administrator. Consistent with FACA regulations, its deliberations are held as public meetings and teleconferences for which advance notice is given in the *Federal Register*. The DFO is present at all such meetings to assure compliance with FACA requirements. Meeting minutes were taken (by DFOs from the SAB Staff Office) for this teleconference. The minutes will be certified by the CASAC (and PM Review Panel) Chair and made available on the SAB Web site ([www.epa.gov/sab](http://www.epa.gov/sab)). All Panelists

have earlier submitted documentation with respect to possible financial conflicts-of-interest, which was reviewed by a SAB staff member prior to the meeting and found to be satisfactory.

Dr. Vanessa Vu, SAB Staff Office Director, thanked the members of the CASAC PM Review Panel for taking part in this review and immediate past CASAC Chair Dr. Phil Hopke (who was not present) in particular. She also thanked the current Chair, Dr. Rogene Henderson, as well as the EPA managers and staff from the Office of Air Quality Planning and Standards (OAQPS), within the Office of Air and Radiation (OAR).

#### Purpose of Meeting and Welcome by OAQPS

Dr. Rogene Henderson, CASAC and PM Review Panel Chair, briefly stated the purpose of the meeting, which was to provide a peer review of the 2<sup>nd</sup> Draft Staff Paper for PM. Mr. John Bachmann then gave a welcome and thanks to the Panel on behalf of the Director of OAQPS, Mr. Steve Page, who was unable to attend this meeting.

#### Overview of EPA's 2<sup>nd</sup> Draft PM Staff Paper & Risk Assessment and Key Issues

Dr. Karen Martin, Mr. Harvey Richmond, and Mr. Mark Schmidt, OAQPS, provided overview presentations on the 2<sup>nd</sup> Draft Staff Paper, the PM Health Risk Assessment, and "Data Analysis in Support of a Revised Secondary PM<sub>2.5</sub> National Ambient Air Quality Standards (NAAQS) Based on Visibility," respectively. (A copy of each of their presentations is found in Appendix C.)

Dr. Martin acknowledged the document authors and provided a summary of the schedule for the PM review that reflects the dates in the consent decree that governs this review. She stated that the notice of proposed rulemaking (draft rule) for the PM NAAQS must be signed by December 20, 2005, and that related rulemaking on monitoring will follow the same schedule. Dr. Martin then provided a chapter-by-chapter summary/overview of the 2<sup>nd</sup> Draft PM Staff Paper. She noted in particular that the approach used to develop staff recommendations on the primary PM<sub>2.5</sub> standards was substantially broadened compared to that used in the last review, based on the more extensive and stronger evidence from long- and short-term exposure studies now available, as well as on the much more extensive PM<sub>2.5</sub> air quality data now available. Dr. Martin added that staff also placed greater reliance on the quantitative risk assessment than in the last review. In contrast, the approach for thoracic coarse particles was far narrower, reflecting the much more limited evidence on health effects and the more limited availability of air quality data. With respect to the staff approach to the primary PM standards, staff identified a series of questions that framed their review that helped to ascertain to what extent new information either reinforces or calls into question the existing standards, or serves to reduce uncertainties or introduces new uncertainties. In addition, these questions focus on identifying ranges of alternative standards that are supportable based on the available evidence and risk assessment. Dr. Martin noted that the welfare chapters were substantially revised from the first draft as a result of advice from the Panel. Staff did new analyses on fine particles and visibility, which led to staff recommendations for consideration of a secondary standard that would be specifically designed to address visibility impairment. Staff brought forward correlations between urban PM<sub>2.5</sub> levels and visibility adequate to support a PM<sub>2.5</sub> indicator for such a standard. In review of

vegetation and ecosystem effects information, staff placed added emphasis on a critical-loads approach. With respect to the general staff approach on secondary standards, staff framed the questions analogous to the framing on the health issues.

In his overview of the PM Health Risk Assessment, Mr. Richmond commented that, in the last PM NAAQS review only a limited risk analysis was conducted in two urban areas, and that now with much more extensive air quality data available, nine urban areas and additional health endpoints have been included. He noted that concentration-response (C-R) functions are most appropriately applied within the range of air quality evaluated in the study; staff did not extrapolate. Mr. Richmond noted that, in most cases, the information does go very close to estimated background levels, but there is substantial uncertainty about C-R function as lower levels are approached. Staff recognizes that different components of PM<sub>2.5</sub> may have different toxicity, and that PM measures reflect the mix in urban areas. Mr. Richmond stated that staff thought it was appropriate to use proportional rollback to adjust air quality distribution to simulate just meeting alternative 24-hour and annual standards. Staff simulated alternative standard for suites of annual and 24-hour standards, adjusted air quality based on three years of data, decreased non-background PM levels on all days by the same percentage, and illustrated annual impact in terms of risk estimates. Adjustments were applied to a single year of PM values and risks were calculated based on a “composite monitor” (value averages across all monitors reporting concentrations on a given day). Staff chose to use the highest monitor approach over the spatial averaging approach as its base case. In addition, the OAQPS risk assessment included sensitivity analyses with hypothetical thresholds for PM<sub>2.5</sub>, and took a weighted average of slope above the hypothetical threshold and slope below the hypothetical threshold to equal the coefficient from the study. With respect to other sensitivity analyses, Mr. Richmond remarked that the distributed lag model for PM<sub>2.5</sub> short-term mortality shows a doubling of risk compared to single day lag estimates. He also noted that risk estimates comparing generalized additive models (GAM) with generalized linear models (GLM) and with different degrees of freedom were included in the sensitivity analyses and the impact on results depended on whether a single- or multi-pollutant model was used. Furthermore, the impact of an “exceptional event” shows very little difference on the impact of short-term mortality. Finally, staff looked at alternative estimates of PM<sub>2.5</sub> background and saw a small- to moderate impact on the estimated risk reductions.

In his briefing on “Data Analysis in Support of a Revised Secondary PM<sub>2.5</sub> NAAQS Based on Visibility,” Mr. Mark Schmidt stated that the Staff Paper visibility analyses made considerable use of the reconstructed light extinction formula (RE) to estimate RE from hourly speciated PM<sub>2.5</sub>, hourly relative humidity, and hourly PM<sub>10-2.5</sub>. Staff used 24-hour speciation profiles applied to hourly PM<sub>2.5</sub> data. In addition, they used continuous PM<sub>2.5</sub> mass data from the EPA network and hourly relative humidity data from the nearest National Weather Service (NWS) site. OAQPS estimated hourly PM<sub>10-2.5</sub> from collocated continuous PM<sub>10</sub>. Mr. Schmidt noted that there was significant correlation between RE and PM<sub>2.5</sub>. Staff focused on sub-daily concentrations in part because the effect of relative humidity is minimized during daylight hours.

#### Update on Coarse-Fraction Particulate Matter (PMc) Monitoring and Relationship to NAAQS

Mr. Tim Hanley, OAQPS, gave an update presentation on coarse-fraction particulate matter (PMc) monitoring and its relationship to the PM NAAQS. (A copy of this presentation is

similarly found in Appendix C.) He remarked that multi-city field studies were conducted using commercially-available PMc technologies. The CASAC Ambient Air Monitoring and Methods (AAMM) Subcommittee reviewed this study in July 2004. EPA has used 20 instruments at three cities (Riverside, CA; Gary, IN; and Phoenix, AZ). Take-home messages from the study were that EPA was able to capture a wide range of PMc concentrations under a variety of seasons and conditions. The difference method appears to be a strong candidate for use as the method of comparison in a performance-based approach for approval of other methods. EPA learned that instruments have good precision and show good correlation between methods. Mr. Hanley commented that there was high sample completeness in the studies (greater than 95%), adding that the air sheds selected were noted for having high PMc values. He noted that results were shared with instrument manufacturers; and, further, that the Office of Research and Development (ORD) is preparing for an additional field study, and will go back to Phoenix to test the next iteration of instruments. A saturation monitor (a new method) will be introduced, as well as continuous monitoring methods. OAQPS intends to request another consultative meeting with the CASAC AAMM Subcommittee to present the results of this additional study, as well as to consult on optimization issues that focus on reducing the resource requirements of the operating monitoring network. A Data Quality Objectives (DQO) process is being used to identify the acceptable level of uncertainty for operating the Agency's PMc monitoring network. Mr. Hanley also discussed how these DQOs were being developed. He noted that approval of PMc reference and equivalent methods (FRM/FEM) is expected to follow a process similar to that which was used in the recent development of new draft PM<sub>2.5</sub> equivalency criteria for continuous methods, adding components for spatial variability. As for PMc network design considerations, Mr. Hanley stated that OAQPS would like multiple objectives, not just attainment and non-attainment decisions. The Agency is challenged by a high degree of spatial and temporal variation in PMc concentration, and because of that EPA needs continuous PMc monitoring to compensate. The PMc network would likely consist of some existing PM<sub>10</sub> sites and some representative urban and rural multi-pollutant sites.

In response to questioning by members of the Panel, Mr. Hanley noted that, in network design, EPA is focusing on multi-pollutant measurements and looking at substantially more species than the criteria pollutants. He also remarked that the Agency will need to strike a balance between continuous monitors and speciation monitoring in the network.

#### Public Comment Period

Mr. Butterfield kicked-off the public comment period by reminding speakers to limit their oral statements to no more than three minutes. (See Appendix D for a summary listing of all public speakers.)

Dr. Gina Solomon [M.D.], Natural Resources Defense Council (NRDC) – Commented that, while the Staff Paper was excellent staff paper, she was not sure the proposal went far enough, and that this framework is exceptionally cautionary. Dr. Solomon noted that EPA could focus on numerous other endpoints, such as emergency room visits, infant mortality, C-reactive protein increases, decreased heart variability, etc. She also remarked that ultrafine particles need to be considered in the next round of PM NAAQS review.

Dr. Michael Lipsett [M.D.], University of California, San Francisco (UCSF) School of Medicine – Dr. Lipsett commented that there does not appear to be much justification presented in this PM Staff Paper for the recommended alternative PMc standards. Standards recommended by staff for consideration are well above the 99<sup>th</sup> percentile of some coarse particle distributions. He stated that staff needs to take into account that if EPA wishes to promulgate a standard that is as high as those recommended, it needs to be adequately justified. Dr. Lipsett remarked that there are a number of relevant PMc studies that are not even noted in the paper. In his opinion, the PM Staff paper does not provide a compelling case for standards so much higher than the air quality levels observed in the studies.

Dr. Mark Frampton [M.D.], University of Rochester [NY] Medical Center – Speaking on behalf of both himself and the American Thoracic Society, Dr. Frampton commended EPA for the research program on PM that has brought the Agency to this point over the last five to six years. While we are in a much better position than we were before, he made two points: (1) the current standards are not protective; and (2) EPA needs to strengthen the PM standards. Dr. Frampton agreed that the recommendations are too lax and need to be more stringent, noting that it is clear from the risk analysis done by EPA that thousands of deaths per year can be prevented by lowering both the short- and long-term PM<sub>2.5</sub> standards. He recommended: reducing loopholes in current standards; eliminating spatial averaging across areas; and changing the 98<sup>th</sup> percentile to the 99<sup>th</sup> percentile to reduce exclusions, adding that these proposed levels are consistent with what California has done. Finally, Dr. Frampton stated that a PMc standard should be considered in the range of 25-30  $\mu\text{g}/\text{m}^3$  at the 99<sup>th</sup> percentile, roughly equivalent to California and the European Union.

Mr. Philip Johnson, Northeast States for Coordinated Air Use Management (NESCAUM) – NESCAUM is recommending Primary PM<sub>2.5</sub> Standards of 12  $\mu\text{g}/\text{m}^3$  (annual) and 30  $\mu\text{g}/\text{m}^3$  (98<sup>th</sup> percentile) (daily). Mr. Johnson noted that either the daily or the annual standard has the ability to shift the distribution of the PM<sub>2.5</sub> ranges, and that annual standards may fail to constrain daily levels and vice versa. He commented that both standards should be maximized to protect as much as possible. Mr. Johnson commented that 72% of the U.S. population lives on 6% of the land mass, and that only 16% of our population lives in areas not meeting PM standards.

Dr. Allen Lefohn, A.S.L. & Associates

Dr. Lefohn's comments represent conclusions reached by Dr. Barry Switzer and himself. He noted several problems in staff paper: No epidemiological support for a 24-hour standard because C-R depends only on time-average exposure; the risk analysis is extremely sensitive to thresholds; and many analyses from the air quality criteria document (AQCD) for PM have unresolved questions. Dr. Lefohn stated that an outcome of adopting the linear response function is that two different distributions of 24 hour PM<sub>2.5</sub> concentrations, having the same annual average (one with relatively uniform hourly average versus one with peaks and valleys), are expected to produce almost identical effects that come from mathematics because of the linear model. He contends that staff has misunderstood the information about spatial variability across sites, having pooled 24-hour data across country in an attempt to illustrate uniformity. Dr. Lefohn suggests that CASAC revisit the definition of policy-relevant background.

Mr. Kurt Blase, O'Connor and Hannan L.L.P. (representing the Coalition for Coarse Particle Regulation) – Mr. Blase noted that he represents six different industry organizations that are interested in the regulation of PMc. He echoes John Bachmann's comments about how important this committee is. With respect to the annual standard, Mr. Blase comments that, in the PM Staff Paper and AQCD, there appears to be a consensus that there is no support for an annual standard for PMc; however, there is a clear consensus against reliance on data for short-term standard for PM<sub>2.5</sub>. He still sees a split on the question of whether the morbidity data supports standards, noting that all these studies are urban studies and involve mixes of pollutants found in urban areas. Mr. Blase stated that his clients in rural areas whose emissions are primarily crustal material wonder why it's reasonable to regulate them on the basis of data from urban areas. He suggests that the data as a whole most clearly support the exclusion of coarse PM from the PM NAAQS until some of these data gaps are filled.

Mr. Greg Shaefer, Arch Coal (representing the Coalition for Coarse Particle Regulation) – Displaying a map showing a drought monitor, Mr. Schaeffer noted dramatic exceedences of PMc when the area is otherwise in compliance with PM<sub>10</sub>. He contends that there is probably some regional equivalence but it is very difficult to come up with national equivalent standards because of the differences in the PM<sub>2.5</sub> to PM<sub>10</sub> ratios.

Ms. Martha Keating, Clean Air Task Force (CATF) – Ms. Keating pointed-out that, as the EPA staff has concluded, hundreds if not thousands of new studies have only strengthened the robust body of research association of PM with health impacts on both adults and children since the promulgation of the PM<sub>2.5</sub> standard in 1997. She noted that Abt Associates has used EPA Science Advisory Board-approved methodology to estimate the damages caused by primary and secondary fine particles from power plants and diesel engines in the US. According to this analysis, there are an estimated 21,000 annual premature deaths attributable to diesel engines and 24,000 annual deaths from power plant particles. Many of these deaths could be avoided if standards were more protective. The CATF supports the proposal to adopt a standard for coarse PM, which is also linked to respiratory and cardiovascular morbidity and mortality. In addition, the CATF supports the staff recommendations to tighten existing standards and supplement them with highly-protective secondary and coarse thoracic particle standards. Ms. Keating also commented that, for future reviews, EPA should work aggressively towards adoption of a short term 1-hour PM<sub>2.5</sub> primary standard. Finally, she noted that ultrafine particles have also been overlooked in this review, and that, for the next review cycle, EPA should consider adoption of an ultrafine particle standard.

Dr. Linda Smith, California EPA Air Resources Board (CARB) – The CARB has reviewed the 2<sup>nd</sup> Draft PM Staff Paper and supports staff's ranges for PM<sub>2.5</sub>. Dr. Smith commented that the CARB recommends a PM<sub>2.5</sub> annual average of 12  $\mu\text{g}/\text{m}^3$  and a 24-hour standard of 25-30  $\mu\text{g}/\text{m}^3$  at the 99<sup>th</sup> percentile. The CARB also recommends that staff consider adding an annual average standard for PMc. Dr. Smith stated that hundreds of studies have been issued on the health effects of PM in over 200 cities in five continents, and that adverse health effects are associated with both short-and long-term exposures. She added that the benefits would include reductions of thousands of deaths, millions of lost work days, etc. Finally, she suggested a PMc standard of 20  $\mu\text{g}/\text{m}^3$ .



Dr. Bart Ostro, California Office of Environmental Health Hazard Assessment (OEHHA) – Dr. Ostro noted that protection of public health suggests a PM<sub>2.5</sub> annual standard of 12  $\mu\text{g}/\text{m}^3$  and a 24-hour standard of 25-30  $\mu\text{g}/\text{m}^3$  at the 99<sup>th</sup> percentile, and a PMc standard less than 75  $\mu\text{g}/\text{m}^3$ . He stated that new studies show little confounding of PM and mortality from temperature or co-pollutants, while the EPA/HEI sponsored reanalysis using non-GAM models continues to show associations between PM and mortality. Finally, Dr. Ostro remarked that they provided recommendations of coarse particle studies that demonstrate many of the associations, specifically, those of mortality and hospital admissions related to coarse particles; therefore, they think a PMc 24-hour standard of 75  $\mu\text{g}/\text{m}^3$  would clearly not be health protective. Regarding PMc 24-hour average, Dr. Ostro would suggest 36-45  $\mu\text{g}/\text{m}^3$  at the 99<sup>th</sup> percentile.

Dr. Anne Smith, Charles River Associates (representing the Utility Air Regulatory Group [UARG]) – Dr. Smith commented that EPA over-adjusts when simulating exact attainment of standards, and that the Agency rather needs to use an appropriate rollback method, since overstated rollbacks equates to overstated benefits. Furthermore, she noted that, with regard to EPA's estimate of long-term mortality avoided at current standard, the mortality benefits go down if you just adjust to exact standards. Dr. Smith noted that a standard integrated uncertainty analysis could be conducted.

Ms. Deborah Shprentz, Consultant to American Lung Association (ALA) – Ms. Shprentz stated that the ALA is very pleased with the latest Staff Paper. The scientific evidence in the AQCD for PM compels EPA to the regulation of fine particles. ALA would discourage any raising of the upper end of the range of the proposed standards, adding that there is considerable mortality at the lower end of the range, which suggests even more stringent standards. She emphasized the importance of considering the EPA staff recommendation of moving to a 99<sup>th</sup> percentile form, stressing that EPA needs to both lower the level as well as changing the form — and adding that the Lung Association actually favors an option of lowering both the annual and 24-hour PM<sub>2.5</sub> standards beyond the two options proposed in the PM Staff Paper, in order to offer a health protective suite of standards. Ms. Shprentz noted that no scientific effect suggests a threshold, and that no researches have been able to identify a threshold. She indicated that ALA would like to see the CASAC recommend that EPA strip their analysis of this hypothetical threshold. Finally, ALA recommends no spatial averaging.

John Balbus [M.D.], Environmental Defense and American Public Health Association (APHA) – Dr. Balbus stated that APHA applauds the EPA for reducing PM exposures over the last 30 years. However, he notes that current PM NAAQS proposals do not go far enough due to the underestimate of risk, for the following four major reasons: (1) too few geographic areas are considered; (2) the PM Staff Paper uses only the single day lag instead of a distributed lag, yet the single day lag underestimates adverse health effects by 50%; (3) the sensitivity analysis uses unsupported thresholds; and (4) EPA ignores significant health endpoints, *e.g.*, morbidity endpoints. The APHA calls on the CASAC to recognize that the science indicates even the most stringent of these current recommendations do not fully protect the health of our infants, children, and adults from harm caused by fine particle air pollution.

Dr. Ron Wyzga, Electric Power Research Institute (EPRI) – Dr. Wyzga spoke about the risk assessment in the PM Staff Paper, stating that he thinks it needs to be as scientifically defensible as possible and must therefore present uncertainties in the most objective way possible. He cites

the Klemm & Mason (2003) paper, which looked at mortality for several causes of death in six cities, noting that the Staff Paper uses this for deaths from ischemic heart disease in St. Louis. Dr. Wyzga also remarks that, using the GAM approach, there is bias in terms of estimating standard error; therefore the confidence interval was probably too small. In this case, one result was taken without consideration of other models, and the confidence interval should have been greater. His own co-authored paper looked at mortality reductions in Philadelphia and said that, for some unknown reason, the coefficient for PM<sub>2.5</sub> was very unstable; Dr. Wyzga noted that staff took one number from that paper, while the rest of the paper was ignored.

Mr. Kyle Kinner, Physicians for Social Responsibility (PSR) – On behalf of PSR, Mr. Kinner conveyed the organization's support for the strongest standard under consideration. He noted that PSR believes that EPA staff scientists have correctly interpreted the substantial and compelling scientific evidence before the Panel that shows significant adverse health impacts related to particulate pollution. Mr. Kinner remarked that recent studies suggest the current standards for PM<sub>2.5</sub> and PM<sub>10</sub> should be lowered. PSR believes tens of thousands of people are at risk, even at levels below current standards. He also recommends against spatial averaging.

Dr. George Lucier, Environmental Defense – Dr. Lucier stated that the evidence is clear that fine particulates are a serious threat at levels below current standards. He noted that the Clean Air Act mandates protection of sensitive subpopulations, but remarked that the PM Staff Paper's recommendations fail to meet this mandate. Dr. Lucier commented that, if PM was not a problem, more studies would diminish concern; however, the opposite is occurring. He made four specific comments: (1) In EPA's risk assessment, no city achieves a greater than 50% reduction in risk, which is only a halfway reduction in risk; (2) for thoracic particles, the scientific evidence supports a standard closer to 25-30  $\mu\text{g}/\text{m}^3$ ; (3) Speculative thresholds presented in the Staff Paper are used in risk assessments; because they are purely hypothetical they should be stricken from the paper; and (4) Environmental Defense strongly supports the elimination or severe restriction of spatial averaging for PM<sub>2.5</sub>, since people's exposures tend to occur in neighborhoods and standards based on regional averages would prevent overexposure in many people.

Dr. Ron Wyzga (for Dr. Naresh Kumar), EPRI – Dr. Wyzga noted that Dr. Kumar's comments are tied to the proposed secondary standard for PM<sub>2.5</sub>. PM mass does not capture the factors that really impact visibility impairment, *i.e.*, relative humidity, size composition of particles, and also the chemical composition of particles, all of which impact visibility. He does not think PM mass is a good indicator of visibility in urban areas, noting that the Staff Paper uses reconstructive light extinction (RE) for PM<sub>2.5</sub> as a measure of visibility; it would be ideal to have good light extinction data for urban areas but these data currently do not exist. Furthermore, he remarked that you find that R<sup>2</sup> values also differ considerably from site to site. Dr. Wyzga's colleague also comments specifically about some of the benefits basis that are used in the Staff Paper, and notes that the data factor are relatively few that have been used and that it may be very difficult to extrapolate them to the population-at-large.

Dr. Rose Marie Robertson [M.D.], American Heart Association (AHA) – Dr. Robertson noted that cardiovascular diseases are the leading cause of death in U.S., and that there is growing epidemiological evidence indicating an increased risk of heart disease with short- and long-term

exposure to PM. After reviewing this evidence, the AHA published a June 2004 statement to make healthcare professionals aware of the increased risk of air pollutants, including particulate matter, for the occurrence of cardiovascular disease events. There was a robust association between long-term PM<sub>2.5</sub> concentrations and overall cardiovascular mortality reported. The largest increase in risk was for ischemic heart disease, coronary artery disease, and the risk for arrhythmias, heart failure, and cardiac arrest mortality were also elevated. This evidence indicates that a more stringent annual average PM<sub>2.5</sub> standard is needed, as proposed in the draft Staff Paper. The AHA specifically supports the lowering of both the 24-hour and the annual average standards for PM<sub>2.5</sub>.

Ms. Tamara Thies, National Cattlemen's Beef Association (NCBA) – Ms. Thies challenged previously-written statements by Panel members Dr. Petros Koutrakis, Dr. Philip Hopke, and Dr. Roger McClellan. She stated that she represents over 1,000,000 ranchers, cattlemen and farmers who will be profoundly impacted by what EPA proposed, and that NCBA counts on the Panel for independent scientific objectivity. Ms. Thies went on to say that her members believe in best management practices and do not oppose reasonable controls; however, most cattlemen would be devastated by coarse PM regulations, citing how one particular cattle operation violated the PM 160 out of 365 days in 2003. Therefore, most of the agricultural economy will be unable to comply.

Mr. Robert Connery, Holland & Hart LLP (representing NCBA) – Mr. Connery remarked that he represents cattlemen who generate fugitive dust from crustal material. He maintains that Panel members could look in this Staff Paper and not find any science supporting 150  $\mu\text{g}/\text{m}^3$  for coarse particles. Mr. Connery went on state that EPA says three studies are significant: Toronto, Seattle and Detroit. He invited the Panel to take a look at these studies, asserting that, in the Shepherd study, 72% and 82% of the PM<sub>2.5</sub> data is missing. The effect of coarse particles disappears in the reanalysis. Mr. Connery asked how one gets evidence of PM<sub>10-2.5</sub> effects without that data, stating that the effect disappears in the reanalysis. He also comments that if one looks at the Toronto and Burnett study, again the effect of coarse particles disappears in the reanalysis. Mr. Connery concluded by telling the Panel that it would be completely arbitrary to include in the standard crustal rural coarse PM fugitive dust.

Mr. Jon Heuss, Air Improvement Resource, Inc. – Mr. Heuss commented that, in 1996, EPA acknowledged large uncertainties in setting PM standards, noting that again in 2005 we have large uncertainties. He remarked that the interpretation of science in Chapter 3 of the PM Staff Paper goes beyond [the state of the science in] the AQCD. Mr. Heuss remarked that risk assessment should not be used to guide selection of standards; and that, while EPA has focused on multi-city studies, they never show the wide range of individual city results within those studies. A wide range does show up in an individual city in HEI reanalysis of Detroit; however, the big question there was GAM versus GLM.

Dr. Suresh Moolgavkar, Sciences International, Inc. (representing the PM Fine Coalition) – Dr. Moolgavkar asked for more balanced treatment in the presentation of the science in the PM Staff Paper, and presented three examples to support his case. The Agency has chosen one coefficient from each of his papers used; the only robust association was with SO<sub>2</sub>. He also noted that, in studies with smaller relative risks and with independent variants, proportion- independent models

may not be the most appropriate bearer of results in these studies. Finally, Dr. Moolgavkar stated that there is absolutely no consideration of the model uncertainty and limitations of observation of these studies of risks and think the Staff Paper needs to be revised to address these issues.

Dr. George Thurston, NYU School of Medicine – Dr. Thurston remarked that it is not simply EPA who dismisses the biological plausibility of SO<sub>2</sub>. He thanked the CASAC and EPA for developing a high-quality PM Staff Paper. Dr. Thurston asked the Panel to please accept a letter signed by a large group of scientists in support of the EPA Staff Paper recommendations regarding the revisions needed to the particulate matter NAAQS as well as the attached list of independent air pollution doctors, researchers, and scientists who have endorsed this letter. This letter was circulated to U.S. and Canadian scientists in the air pollution research field, including the authors of many of the significant papers considered in the EPA review. He noted that there is a broad scientific consensus that the PM standards need to be strengthened, and that scientists agree that EPA has correctly interpreted their research.

Casimer Andary, Alliance of Automobile Manufacturers (AAM) – Mr. Andary noted that he is speaking on behalf of an industry trade association that represents 80% of vehicles in the U.S. He cited a number of scientific studies that show pollution from mobile sources causes problems but asserted that there are problems with these studies. Mr. Andary remarked that exhaust emissions from both gasoline and diesel vehicles continue to be subject to stringent controls despite the existence of confounding factors. In addition, PM<sub>10</sub> emissions were reduced by 94% since 1970, and EPA documents that peak CO air quality has improved by 75% since 1975. This includes the effects of increasing number of vehicles and vehicle miles traveled. Mr. Andary commented that an important message is that one has to consider the time and place of the study to ascertain whether mobile source emissions are relevant, and that it is not known which sources are contributing to PM health effects. Therefore, a number of companies of the Alliance strongly support a systematic approach to identify and mitigate any potential PM health effects contributors.

Dr. Kenny Crump, ENVIRON Health Sciences Institute – Dr. Crump noted that he was there at the request of the Engine Manufacturers' Association (EMA) but that his comments were his own. He stated that he thought the PM Staff Paper shows evidence of a great deal of hard work. Nevertheless, there are possible biases for overestimating and underestimating risk. In general, Dr. Crump thinks the selection of studies to include in the risk assessment should not be based on association in the study or in effect and the current move to remove studies that show less effect does not satisfy the requirement, and he thought that the argument for eliminating certain studies was not convincing. Furthermore, not accounting for distributed lag creates opposite bias. He maintains that there are insufficient reasons for using a single background for the entire Eastern U.S., and that using the lowest measured level in place of the background does not really address the relevant policy issues. Also, a percentage reduction in risk is not an adequate metric for standards; one needs to look at what the residual risk is under the standard. Dr. Crump's final point is that the method for evaluating alternative standards was based primarily on a percentage reduction in risk, and he stated that this is not an adequate measurement to make for determining that the public is protected with an adequate margin of safety. Rather, he thinks that one has to look at what is the risk under the standard and what is the residual risk.

There was opportunity for questions-and-answers between the presenters and the members of the Panel following each of these presentations.

### Summary of CASAC PM Review Panel Discussion and Deliberations re: the 2<sup>nd</sup> Draft PM Staff Paper

#### **Chapter 2 (Characterization of Ambient PM)**

Overall, Panel members found Chapter 2 to be very well written that competently summarized the information in the PM AQCD, with one member commenting that the chapter displayed a sophisticated understanding of what we know about particles.

Some of the specific issues and concerns with Chapter 2 expressed by Panel members were as follows:

- The document addresses the differences in the concentration as measured by different monitors in different cities, but does not talk about very high concentrations which exist near freeways, which may have important implications for the standard.
- The chapter should, with respect to policy-relevant background level: include PM sources from Canada and Mexico; not ignore sulfate; and blue haze in the Smoky Mountains.
- It would be nice to know the statistical distribution of background and statistical distribution of non-background, and how they relate to each other on a short-term basis, as well as the distribution of background versus anthropogenic PM.
- Regarding exposure assessment, the discussion of heterogeneity in the Staff Paper showing site-to-site comparisons isn't relevant.
- Background levels of PM were not consistently reported (with one member asking [rhetorically] how much the background varies by season, and why would one use the annual background if there are seasonal differences in background).
- More detailed characterization of composition of PM is needed, in addition to its relationship to site-by-site variation within a given region.
- The Staff Paper tends to minimize the issue of composition, which then leads to the position of saying that linear rollback will take care of things; and compositional differences suggest that there might not be consistency with the mean.

#### **Chapter 3 (Policy-Relevant Assessment of Health Effects Evidence)**

The Panel had significant comments on Chapter 3, but felt overall that the chapter did not need to be completely redrafted. Panelists agreed that there is not a strong basis for an annual coarse PM standard, but that the scientific evidence does exist to support a short-term standard for PM<sub>10-2.5</sub>. One member commented that it would be irresponsible not to push for a coarse particle standard, while another Panelist noted that PM<sub>10</sub> evidence exists in areas where fine PM levels are very low.

Some of the specific issues and concerns that the members of the Panel had with regard to Chapter 3 were as follows:

- There are a few areas in the chapter where there is either understatement or overstatement of relevant information (*e.g.*, one member expressed in particular that the summary of findings and the associated interpretation was overstated).
- With respect to statistical comparisons, staff needs to provide greater clarity in their specification of PM variables.
- A concentration-response threshold should not always be assumed (with one Panelist commenting that the PM AQCD appropriately stated that there is no evidence to state that one does or does not exist) and therefore C-R thresholds should be treated in a neutral way, neither for nor against.
- One Panel member commented that staff needs to consider short-term mortality effects of coarse particles, remarking that excluding mortality of coarse particles is “on thin ice.”
- The integrated assessment of health evidence is not well done, and is misinterpreted as “strength of association.”
- The chapter is missing the tremendous progress or evolution in the state of the science since 1997. It also does not reflect the fact that combustion particles can be more toxic than non-combustion particles; epidemiologic studies show the difference between particles, and toxicology and composition were underplayed in this chapter.
- The discussion of sensitive populations in this chapter actually reflects what was in the PM AQCD, but the concluding sentences don’t reflect enough about these subgroups, and the AQCD was much more equivocal on the new evidence on socio-economic status.

#### **Chapter 4 (Characterization of Health Risks)**

The members of the Panel generally complimented staff on Chapter 4, with one Panelist noting that the understanding of the variability and uncertainty is the most important piece of this chapter. As with the discussion on Chapter 3, Panel members discussed a short-term PM<sub>10-2.5</sub> standard, with one Panelist remarking that there is a sufficient basis for recommending the setting of a coarse particulate matter standard on the basis of morbidity data alone, and that it is not necessary to claim a mortality effect as well.

Some of the specific issues and concerns with Chapter 4 expressed by Panelists were as follows:

- Readers need to understand how adequately the central monitors reflect the population exposures, with the assumption that population risk is distributed uniformly across the population.
- The variability within a site and the variability in the composition of material in PM is not discussed in this chapter. While the staff is to be commended for doing a sensitivity analysis on the impact of varying background levels, there is simply not enough data at low levels. This chapter demonstrated how robust the risk estimates are to alternative background levels; thus, understanding the background becomes less important.
- Chapters 3 and 4 demonstrate that there is risk in the current population for the current levels of PM<sub>2.5</sub> that exist and that reducing PM<sub>2.5</sub> can lead to reduction of morbidity and mortality — a conclusion that is pretty solid. However, additional discussion is needed on the uncertainty in the numbers of lives saved, especially for PM<sub>10-2.5</sub>. More discussion is also needed on the composition of coarse particles.
- The chapter needs to be clearer and shortened, which would make it less difficult to read; and the discussion concerning uncertainty is not pulled-together in a multi-factorial way.

- There is a “woeful” state of knowledge on thresholds.
- More air quality data need to be presented which comes from the PM monitors in order to gain a sense of the variability, which would contribute to a better understanding of the amount of uncertainty.
- The discussion of sensitivity analysis should be brought forward in the chapter rather than relegated to the appendices.

The DFO adjourned the meeting for the day at approximately 5:45 PM.

## **THURSDAY, APRIL 7, 2005**

### Reconvene Meeting, Call Attendance

Mr. Butterfield, reopened the teleconference, called attendance, and welcomed all attendees back to the second day of the meeting.

### Re-cap of Previous Day’s Meeting

Dr. Henderson suggested that the Panel move directly into the second day’s public comment period, the purpose of which is to permit members of the public who were unable to provide their oral comments on the first day with an opportunity to do so.

### Additional Public Comment Period (April 7, 2005)

Mr. Butterfield kicked-off the public comment period by reminding speakers to limit their oral statements to no more than three minutes. (See Appendix D for a summary listing of all public speakers.)

Dr. Katherine Shea [M.D.], University of North Carolina (UNC), Chapel Hill (representing the American Academy of Pediatrics [AAP]) – Dr. Shea commented that: 15 million children live in areas which fail to meet 1997 PM standards; particulate matter impacts the ability of children’s lungs to grow, regardless of history of asthma; reduced lung function is irreversible; PM also leaves chronic cough and other symptoms; 90% of alveoli in lung are formed after birth, and developing lungs are highly susceptible to air pollutants; increased exposure because children play outdoors; and the cost of treating asthma was \$3.2 billion per year. The 2004 statement by the AAP points-out that the law requires protection of the most vulnerable. Therefore, standards should include a margin of safety to protect children. The AAP urges EPA to adopt an annual PM<sub>2.5</sub> standard of 12  $\mu\text{g}/\text{m}^3$ ; commenting also that fewer pollution days and a 24-hour PM<sub>2.5</sub> standard of 25  $\mu\text{g}/\text{m}^3$  are needed.

Dr. Bonnie New [M.D.], Health Professionals for Clean Air – Dr. New remarked that, as a doctor, she has seen first-hand the panic on the face of a child suffering from an asthma attack. She stated that the second draft of the PM Staff Paper represents a valid review of past and recent research on the health effects of particulate pollution, and that this research provides strong evidence that the current annual and 24-hour average standards are not protecting the health of

Americans and must therefore be strengthened. Dr. Shea supports the recommendations in the EPA Staff Paper that strengthen the level and the form of the standards and comments that the levels of the standards that are recommended by staff are scientifically sound.

There was opportunity for questions-and-answers between the presenters and the members of the Panel following each of these presentations.

#### Additional OAPQS Comments

Dr. Martin did not have any comments from yesterday's discussion.

#### Summary of CASAC PM Review Panel Discussion and Deliberations re: the 2<sup>nd</sup> Draft PM Staff Paper

##### **Chapter 5 (Staff Conclusions and Recommendations on Primary PM NAAQS)**

The Panel held extensive discussions on Chapter 5. Overall, Panel members felt that staff had done a very good job in summarizing the key issues and made reasonable judgments with respect to the indicators, averaging times, statistical form, and levels of any potential short-term and long-term PM<sub>2.5</sub> NAAQS.

Some of the specific issues and concerns that the members of the Panel had regarding Chapter 5 were as follows:

- One member commented that the entire chapter takes an approach to try to focus on a range of sensible standards but needs to be seen in broader context. He noted that several constraints are: (1) the inability to consider costs; (2) the inadequate nature of risk assessment which does not account for the degree of uncertainty that exists in many aspects of the data used for C-R function. He remarked that the Staff Paper uses sensitivity analysis but that this does not capture the uncertainty that exists in any formal way.
- With respect to the threshold issue, since it is not known whether there even is a threshold, the staff assumed the lowest measured level is the threshold. One Panel member stated that he would choose a distribution, adding that there must be an inflection point and an S-shaped curve.

There was a wide-ranging discussion on whether the Agency should be proposing a coarse PM standard (*i.e.*, PM<sub>10-2.5</sub>). A Panel member argued that, while it was agreed that PM<sub>10</sub> is a poor surrogate for coarse PM, having a "placeholder" is satisfactory until better information is available. This placeholder PMc standard should provide an approximately-equivalent degree of health protection as the previous PM<sub>10</sub> standard. He added that the state of the science will improve in the future with improved epidemiology, including source apportionment, as well as continuous monitoring. Panel members discussed "exceptional events," fugitive dust policies, and the nature of crustal PM, which is found in non-urban settings and differs substantially in both composition and toxicity from urban PM. One Panel member suggested an urban PMc standard rather than national PMc standard which would include non-urban areas, noting that



coarse-particle composition should be the determining factor, and that a PMc standard should allow for some flexibility. Members of the Panel discussed the toxicology and epidemiology of PM<sub>10-2.5</sub>, with one member commenting on the “irritant effects” of PMc. Another member contrasted this with “road dust,” which is highly toxic, and contains combustion particles, metals, latex, engine oils, sulfate and nitrate, endotoxins, etc. This Panelist also commented that it makes sense to have a PMc standard that applies only to urban areas, since urban dust is not generally transported over large distances.

Another Panelist acknowledged that a high degree of scientific uncertainty surrounds setting standard in this area, coupled with a limited set of data, making it very difficult to consider a national PMc standard. He went on to note that putting out a standard with so many exceptions is also problematic, as the line between urban and rural is very vague, and added that neither variability in composition nor spatial variability are well understood. The Panel discussed the difficulties in defining urban versus rural dust. When asked whether it was possible to eliminate crustal dust, staff responded that there are alternative ways in which the Agency could address narrowing the focus of a standard intended to protect against thoracic coarse particles, to include choosing different types of policies or monitoring approaches, having a more-detailed definition of the indicator of the standard, or defining the indicator for the standard in more than just size.

One Member acknowledged that there was a tremendous amount of uncertainty about PMc based on its composition, adding that the lack of homogeneity across cities is also a quandary, such that setting a national PMc standard for material for which there is such widely-varying composition is problematic. Conversely, another Panelist commented that having no standard means that there will be no monitoring, noting that if the academic community wants the information, there must be a coarse PM standard. Another member proposed that the research needs captured in the latter part of Chapter 5 appropriately encompass the subject matter on which the Panel has been deliberating.

The Panel also considered the possibility of recommending a change in the short-term PM<sub>2.5</sub> standard and not the long-term (annual) standard. A Panel member remarked that the real driver in terms of mortality is related to long-term exposure; and that, by affecting the short-term standard, the Agency would obviously be impacting long-term levels as well. Another Panelist stated that any change should be based on evidence; short-term effects drive health endpoints, the evidence indicates that there are adverse health effects in the short-term. Still another Panel member pointed-out that NESCAUM’s analysis showed short-term health effects would be the greater driver of the two, but that it is not exclusively controlling. Members did not agree as to whether short-term or long-term PM<sub>2.5</sub> exposures were the principle driver of adverse health impacts, and a lengthy discussion ensued.

With respect to PM<sub>2.5</sub>, the discussion turned to statistical form, with one Panel member commenting that he saw no advantage of the 99<sup>th</sup> over 98<sup>th</sup> percentile for the long-term. Another member added that, the last time that the PM standard was reviewed (1996-1997), EPA presented a good case for why it should be the 98<sup>th</sup> percentile and not the 99<sup>th</sup> percentile, *i.e.*, numbers are unstable at the 99<sup>th</sup> percentile, but at the 98<sup>th</sup> percentile are more robust. The Panel discussed spatial averaging and “highest monitor” techniques. Given the discussion, one member recommended that the Panel come up with a combined suite of PM<sub>2.5</sub> standards which

includes both annual and 24-hour standards, and that the Panel narrow the range to 30-35  $\mu\text{g}/\text{m}^3$  for the 24-hour standard, with a 98<sup>th</sup> percentile form, and 13-14  $\mu\text{g}/\text{m}^3$  for the annual standard. It was noted that there was much more evidence on short-term effects where the evidence suggests we should reduce it. The Panel also discussed the option of keeping the annual standard at its present level of 15  $\mu\text{g}/\text{m}^3$ , which it did not endorse.

#### **Chapter 6 (Policy-Relevant Assessment of PM-Related Welfare Effects), and Chapter 7 (Staff Conclusions and Recommendations on Secondary PM NAAQS)**

The Panelists felt that, overall, Chapters 6 and 7 were very well done. Chapter 6 represented a concise reflection on the key science as presented in the PM AQCD as it pertains to vegetation. One Panel member thought the ecological risk assessment was reasonable given the criteria pollutant approach; however, this approach has serious shortcomings when it comes to protecting ecosystems in the U.S., adding that forest ecosystems are now showing severe symptoms of nitrogen saturation, the result of reactive nitrogen accumulating over time. He went on to state that the forest ecosystem deterioration issue is more complex than nitrogen accumulation; that the long-term cumulative deposition of nitrate exceeds the natural buffering capacity of the ecosystem (with the key implication that PM deposition is only partially-responsible for these observed effects, and that its exact role needs to be determined); and that the criteria pollutant approach should be replaced by the European approach of “critical loads” when it comes to ensuring protection of vegetation and ecosystems in U.S.

Another Panelist commented at length concerning visibility. This member also took issue with EPA’s criteria-pollutant approach, adding that the notion of multiple pollutants and multiple effects is beginning to sink in. He remarked that the PM Staff Paper shows some continuing bias in its thought processes which are the result of the traditions surrounding our science, especially relating to the concept of deposition (*i.e.*, acid, acidic, and acidifying); and also spoke about the adverse ecological impacts of ammonia, the principal sources of which are animal agriculture.

Commenting on Chapter 7, a third member commended EPA for moving forward with the proposed ranges of elements of a secondary standard for visibility, noting that staff’s work was very thoroughly documented and had a sound basis. He added that it is very significant to consider that this is different from the regional haze regulations.

Some of the specific issues and concerns that Panelists expressed with respect to Chapters 6 and 7 were as follows:

- One member commented that, with respect to visibility, he felt it would be inappropriate to force a national standard based on visibility on Eastern cities. Other Panel members did not agree with this member on this issue.
- Another Panelist remarked that the current secondary standard is unacceptable, in that it is not protective of visibility values — and not simply “dollars” but the welfare impacts of greatly-reduced visual range which currently is occurring in many locations across the country. Furthermore, he noted that the structure of the standard has nothing to do with visual range, adding that 24-hour averages are not informative in terms of most of our viewing experiences.

Summary, Wrap-up, Next Steps and Closing Remarks

The Chair asked each of the lead-discussant pairs for each chapter of the PM Staff Paper to work jointly in drafting the corresponding section of the Panel's letter/report to the EPA Administrator for that chapter which represents a synthesis of their own views, the preliminary (or revised) written review comments from other members, and the Panel's deliberative discussions from this public meeting. In addition, the Chair and the DFO requested that all Panel members provide any additional individual review comments — either your initial submission, or a revision to your preliminary comments previously submitted — to the lead discussants for the applicable chapters, as well as to both the Chair and the DFO. Each member of the Panel was also reminded to furnish comments on the Staff Conclusions and Recommendations on the Primary [human health effects] and Secondary [welfare effects] PM NAAQS found in Chapters 5 and 7 of the PM Staff Paper, respectively. In view of the need to produce this consensus letter/report from this meeting for transmittal to the EPA Administrator as soon as practicable, all these inputs are requested to both the Chair and the DFO no later than Friday, April 15.

Finally, the DFO mentioned that he would schedule a three-hour public teleconference in early May for the members of the CASAC PM Review Panel to discuss this draft final letter/report to the Administrator. The individual review comments of Panel members will be provided in an appendix to that letter/report.

The DFO adjourned the meeting at approximately 3:00 PM.

[Update: On May 18, 2005, the CASAC PM Review Panel held a public teleconference to review and approve the Panel's draft report from its April 6-7, 2005 meeting. Each of the CASAC PM Review Panelists concurred on the final letter/report from the Panel's April 6-7 meeting (EPA-SAB-CASAC-05-007), which was sent to the Administrator under the signature of the CASAC Chair, Dr. Rogene Henderson, dated June 6, 2005. This report is posted on the SAB Web page at the following URL: <http://www.epa.gov/sab/pdf/casac-05-007.pdf>.]

Respectfully Submitted:

Certified as True:

/s/

/s/

*Fred A. Butterfield, III*

*Rogene Henderson, Ph.D.*

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Fred A. Butterfield, III  
CASAC DFO

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Rogene Henderson, Ph.D.  
CASAC Chair

Date: July 29, 2005

## **APPENDICES**

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- Appendix A: Roster of the CASAC Particulate Matter Review Panel
- Appendix B: Meeting Agenda
- Appendix C: April 6, 2006 Presentations on: Overview of EPA's 2<sup>nd</sup> Draft PM Staff Paper & Risk Assessment and Key Issues [Dr. Karen Martin, Mr. Harvey Richmond, and Mr. Mark Schmidt, OAQPS]; and Update on Coarse-Fraction Particulate Matter (PM<sub>c</sub>) Monitoring and Relationship to National Ambient Air Quality Standards (NAAQS) [Mr. Tim Hanley, OAQPS]
- Appendix D: List of Public Speakers

## **Appendix A – Roster of the CASAC Particulate Matter Review Panel**

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**U.S. Environmental Protection Agency  
EPA Science Advisory Board (SAB) Staff Office  
Clean Air Scientific Advisory Committee (CASAC)  
CASAC Particulate Matter (PM) Review Panel\***

### **CHAIR**

**Dr. Rogene Henderson**, Scientist Emeritus, Lovelace Respiratory Research Institute, Albuquerque, NM

### **MEMBERS**

**Dr. Ellis Cowling\***, University Distinguished Professor-at-Large, North Carolina State University, Colleges of Natural Resources and Agriculture and Life Sciences, North Carolina State University, Raleigh, NC

**Dr. James D. Crapo\***, Professor, Department of Medicine, Biomedical Research and Patient Care, National Jewish Medical and Research Center, Denver, CO

**Dr. Philip Hopke\*\***, (Immediate Past CASAC Chair), Bayard D. Clarkson Distinguished Professor, Department of Chemical Engineering, Clarkson University, Potsdam, NY

**Dr. Jane Q. Koenig**, Professor, Department of Environmental Health, School of Public Health and Community Medicine, University of Washington, Seattle, WA

**Dr. Petros Koutrakis**, Professor of Environmental Science, Environmental Health, School of Public Health, Harvard University (HSPH), Boston, MA

**Dr. Allan Legge**, President, Biosphere Solutions, Calgary, Alberta

**Dr. Paul J. Liroy**, Associate Director and Professor, Environmental and Occupational Health Sciences Institute, UMDNJ - Robert Wood Johnson Medical School, NJ

**Dr. Morton Lippmann**, Professor, Nelson Institute of Environmental Medicine, New York University School of Medicine, Tuxedo, NY

**Dr. Joe Mauderly**, Vice President, Senior Scientist, and Director, National Environmental Respiratory Center, Lovelace Respiratory Research Institute, Albuquerque, NM

**Dr. Roger O. McClellan**, Consultant, Albuquerque, NM

**Dr. Frederick J. Miller\***, Consultant, Cary, NC

**Dr. Günter Oberdörster**, Professor of Toxicology, Department of Environmental Medicine, School of Medicine and Dentistry,

**Mr. Richard L. Poirot\***, Environmental Analyst, Air Pollution Control Division, Department of Environmental Conservation, Vermont Agency of Natural Resources, Waterbury, VT

**Dr. Robert D. Rowe**, President, Stratus Consulting, Inc., Boulder, CO

**Dr. Jonathan M. Samet**, Professor and Chair, Department of Epidemiology, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD

**Dr. Frank Speizer\***, Edward Kass Professor of Medicine, Channing Laboratory, Harvard Medical School, Boston, MA

**Dr. Sverre Vedal**, Professor of Medicine, National Jewish Medical and Research Center, Denver, CO

**Mr. Ronald H. White**, Research Scientist, Epidemiology, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD

**Dr. Warren H. White**, Visiting Professor, Crocker Nuclear Laboratory, University of California - Davis, Davis, CA

**Dr. George T. Wolff**, Principal Scientist, General Motors Corporation, Detroit, MI

**Dr. Barbara Zielinska\***, Research Professor, Division of Atmospheric Science, Desert Research Institute, Reno, NV

#### **SCIENCE ADVISORY BOARD STAFF**

**Mr. Fred Butterfield**, CASAC Designated Federal Officer, 1200 Pennsylvania Avenue, N.W., Washington, DC, 20460, Phone: 202-343-9994, Fax: 202-233-0643 ([butterfield.fred@epa.gov](mailto:butterfield.fred@epa.gov)) [Physical/Courier/FedEx Address: Fred A. Butterfield, III, EPA Science Advisory Board Staff Office (Mail Code 1400F), Woodies Building, 1025 F Street, N.W., Room 3604, Washington, DC 20004, Telephone: 202-343-9994]

\* Members of the statutory Clean Air Scientific Advisory Committee (CASAC) appointed by the EPA Administrator

\*\* Immediate past CASAC Chair

## Appendix B – Meeting Agenda

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**U.S. Environmental Protection Agency  
Clean Air Scientific Advisory Committee (CASAC)  
CASAC Particulate Matter (PM) Review Panel**

**Public Meeting & Teleconference  
Wednesday, April 6, 2005 – 9:00 a.m. to 5:30 p.m. Eastern Time  
Thursday, April 7, 2005 – 8:30 a.m. to 3:00 p.m. Eastern Time**

**Marriott Durham Civic Center Hotel  
210 Foster Street, Durham North Carolina, 27701**

### **Peer Review of EPA's 2<sup>nd</sup> Draft Particulate Matter (PM) Staff Paper and 2<sup>nd</sup> Draft PM Risk Assessment**

#### **Final Meeting Agenda**

#### **Wednesday, April 6, 2005**

9:00 a.m.	<b>Convene Meeting; Call Attendance; Introductions and Administration; and Overview of Meeting Agenda</b>	Mr. Fred Butterfield, CASAC Designated Federal Officer (DFO)
9:10 a.m.	<b>Welcome &amp; Opening Remarks</b>	Dr. Vanessa Vu, EPA Science Advisory Board (SAB) Staff Office Director
9:15 a.m.	<b>Purpose of Meeting</b>	Dr. Rogene Henderson, Chair
9:20 a.m.	<b>Welcome from EPA's Office of Air Quality Planning and Standards (OAQPS)</b>	Mr. Steve Page (tentative), Director, OAQPS
9:25 a.m.	<b>Presentations on Overview of EPA's 2<sup>nd</sup> Draft PM Staff Paper &amp; Risk Assessment and Key Issues</b>	Dr. Karen Martin, Dr. Mary Ross, Mr. Harvey Richmond, & Mr. Mark Schmidt, OAQPS
10:30 a.m.	<b>Update on Coarse-Fraction Particulate Matter (PM<sub>c</sub>) Monitoring and Relationship to National Ambient Air Quality Standards (NAAQS)</b>	Mr. Tim Hanley, OAQPS
10:40 a.m.	<b>Break*</b>	
10:55 a.m.	<b>Public Comment Period</b>	Mr. Butterfield (Facilitator)
12:30 p.m.	<b>Lunch (Hotel)</b>	

\*Note: Periodic breaks will be taken as necessary and at the call of the Chair.

**Wednesday, April 6, 2005 (continued)**

1:30 p.m.	<b>CASAC PM Review Panel Discussion and Deliberations: <i>Air Quality</i> (Chapter 2)</b>	Dr. Henderson, PM Review Panel Members
2:30 p.m.	<b>CASAC PM Review Panel Discussion and Deliberations: <i>Human Health Effects</i> (Chapters 3-5; PM Risk Assessment)</b>	Dr. Henderson, PM Review Panel Members
5:15 p.m.	<b>Summary, Wrap-Up and Next Steps</b>	Dr. Henderson
5:30 p.m.	<b>Adjourn Meeting for the Day</b>	Mr. Butterfield

**Thursday, April 7, 2005**

8:30 a.m.	<b>Reconvene Meeting; Call Attendance</b>	Mr. Butterfield
8:35 a.m.	<b>Re-cap of Previous Day's Meeting</b>	Dr. Henderson
8:45 a.m.	<b>Public Comment Period*</b>	Mr. Butterfield (Facilitator)
9:00 a.m.	<b>Additional OAQPS Comments</b>	Dr. Martin
9:05 p.m.	<b>Continue CASAC PM Review Panel Discussion and Deliberations: <i>Human Health Effects</i> (Chapters 3-5; PM Risk Assessment)</b>	Dr. Henderson, PM Review Panel Members
10:15 a.m.	<b>Break**</b>	
10:30 a.m.	<b>CASAC PM Review Panel Discussion and Deliberations: <i>Welfare Effects</i> (Chapters 6 &amp; 7)</b>	Dr. Henderson, PM Review Panel Members
12:00 p.m.	<b>Lunch (Hotel)</b>	
1:00 p.m.	<b>Continue CASAC PM Review Panel Discussion and Deliberations: <i>Welfare Effects</i> (Chapters 6 &amp; 7)</b>	Dr. Henderson, PM Review Panel Members
2:45 a.m.	<b>Summary, Wrap-Up, Next Steps and Closing Remarks</b>	Dr. Henderson
3:00 p.m.	<b>Adjourn Meeting</b>	Mr. Butterfield

**Notes:**

\*The purpose of the public comment period on the second day of the meeting is to permit members of the public who were unable to provide their oral comments on the first day with an opportunity to do so.

\*\*Periodic breaks will be taken as necessary and at the call of the Chair.



**Appendix C – April 6, 2005 OAQPS Overview (2<sup>nd</sup> Draft Staff Paper) & Update (PMc Monitoring) Presentations**

# Overview of 2nd Draft PM Staff Paper

Dr. Karen Martin  
Office of Air Quality Planning and Standards  
U.S. EPA

Clean Air Scientific Advisory Committee Meeting  
CASAC Particulate Matter Panel  
April 6-7, 2005

## ***Topics to be covered:***

- PM NAAQS review schedule
- Overview of changes made to air quality, health-related, and welfare-related chapters
  - Focus on approaches to developing staff recommendations on primary and secondary standards
- Overviews of key analyses:
  - PM Health Risk Assessment (*Harvey Richmond*)
  - Analysis relating PM<sub>2.5</sub> concentrations in urban areas to visibility impairment (*Mark Schmidt*)

## ***PM NAAQS review schedule***

- Final PM Air Quality Criteria Document (AQCD): October 2004
- Completion of PM Staff Paper:
  - First draft PM Staff Paper released August 2003; CASAC review meeting held November 2003
  - Second draft PM Staff Paper: released for CASAC review and public comment on January 31, 2005
  - CASAC review meeting: April 6-7, 2005
  - Final PM Staff Paper: by June 30, 2005
- Rulemaking on PM NAAQS (standards and appendices on interpretation of standards and measurement methods):
  - *Federal Register* proposal to be signed by December 20, 2005
  - Public comment period: 90 days
  - Final *Federal Register* notice to be signed by September 27, 2006
- Related rulemaking on monitoring (requirements for approval of reference and equivalent methods, quality assurance, and network design)
  - Rulemaking notices planned for publication under the same schedule

## ***Overview of Air Quality chapter***

- Additional information provided in Chapter 2 on:
  - PM composition (e.g., example composition of PM<sub>10-2.5</sub> and PM<sub>0.1</sub>; seasonal patterns in PM<sub>2.5</sub> composition)
  - Episodic events
  - PM background levels
  - Relationship between ambient PM and visibility impairment
- Clearer distinctions made between different size fractions to the extent allowed by limited data on PM<sub>10-2.5</sub>, especially with regard to exposure-related issues

## ***Overview of Health-related chapters***

- Integrative synthesis in final PM AQCD provided basis for a more cohesive discussion of health effects in Chapter 3
  - Drew clearer distinctions between PM<sub>2.5</sub>, PM<sub>10-2.5</sub>, and PM<sub>10</sub> in characterizing evidence of effects
  - Summarized integrative evaluation and causal inferences, focusing on evaluative criteria used in the final AQCD
- Discussion of key issues relevant to staff's interpretation and quantitative assessment of the health evidence
  - Air quality measurement and exposure error
  - Model specification
  - Confounding and effect modification
  - Temporality in concentration-response relationships
  - Nature of concentration-response functions and potential population thresholds

## ***Overview of Health-related chapters (cont.)***

- Additional information presented in Chapter 4:
  - Risk assessment results from analyses associated with just meeting various alternative standards and combinations of standards for PM<sub>2.5</sub> and alternative 24-hour standards for PM<sub>10-2.5</sub>
  - National and city-specific baseline mortality rates and city-specific hospitalization rates and population statistics presented
- Emphasis given to discussion and sensitivity analyses of hypothetical population thresholds for PM<sub>2.5</sub>, and PM<sub>10-2.5</sub>
- Sensitivity analyses expanded
  
- Approach to developing staff recommendations on primary standards in Chapter 5 has been substantially revised to include evidence-based and quantitative risk-based considerations
  - Updated integrative evaluation of health evidence in final PM AQCD
  - Additional information from health risk assessment

## ***Approach to developing staff recommendations on primary standards***

- Focus separately on fine and thoracic coarse particles
- Approach for fine particles builds upon and broadens evidence-based approach used in last review in setting PM<sub>2.5</sub> standards
  - In last review, used evidence primarily from short-term exposure studies, as well as considering evidence from long-term exposure studies, as basis for setting a “generally controlling” annual standard and a “supplemental” 24-hour standard
  - Risk assessment judged to be too limited to use as quantitative basis for standards, although it provided qualitative insights
- Broader approach for PM<sub>2.5</sub> based on more extensive and stronger evidence on health effects related to both short- and long-term exposure to PM<sub>2.5</sub>, together with much more extensive PM<sub>2.5</sub> air quality data, now available
  - Greater reliance placed on risk assessment
  - Greater emphasis on evidence from long-term exposure studies
  - No *a priori* focus on a generally controlling annual standard
- Approach for thoracic coarse particles far more narrow, reflecting limited evidence on health effects and PM<sub>10-2.5</sub> air quality data

## ***Approach to primary standards . . . framing questions***

- Adequacy of current standards
  - ☐ To what extent does new information reinforce or call into question evidence of associations identified in last review and/or elements of the standards?
  - ☐ Have important uncertainties been reduced and have new uncertainties emerged?
- If revision is suggested, does available evidence support consideration of standards that are either more or less protective?
  - ☐ Does evidence of associations extend to air quality levels as low as or lower than previously observed?
  - ☐ Are health risks estimated in areas that meet current standards? Are risks important from a public health perspective?
  - ☐ What important uncertainties are associated with evidence and estimated risks?
- If evidence supports consideration of revised standards, what ranges of standards are supportable?
  - ☐ What ranges are supported by the evidence?
  - ☐ To what extent do alternative standards reduce estimated risk?



## ***Approach to primary PM<sub>2.5</sub> standards . . . evidence-based considerations***

	<b>Annual standard</b>	<b>24-hour standard</b>
<b>Long-term exposure studies</b>	<ul style="list-style-type: none"><li>▪ <i>Evidence-based</i> assessment of protection from effects related to <u>long-term exposures</u></li></ul>	
<b>Short-term exposure studies</b>	<ul style="list-style-type: none"><li>▪ <i>Evidence-based</i> assessment of protection from effects related to <u>short-term exposures</u></li></ul>	<ul style="list-style-type: none"><li>▪ <i>Evidence-based</i> assessment of protection from effects related to <u>short-term exposures</u></li></ul>

## ***Approach to primary PM<sub>2.5</sub> standards . . . evidence- and risk-based considerations***

	Annual standard	24-hour standard
Long-term exposure studies	<ul style="list-style-type: none"><li>▪ <i>Evidence-based</i> assessment of protection from effects related to <u>long-term exposures</u></li><li>▪ <i>Risk-based</i> assessment of extent to which alternative suites of standards would likely reduce estimated risks from <u>long-term exposures</u></li></ul>	
Short-term exposure studies	<ul style="list-style-type: none"><li>▪ <i>Evidence-based</i> assessment of protection from effects related to <u>short-term exposures</u></li><li>▪ <i>Risk-based</i> assessment of extent to which alternative suites of standards would likely reduce estimated risks from <u>short-term exposures</u></li></ul>	<ul style="list-style-type: none"><li>▪ <i>Evidence-based</i> assessment of protection from effects related to <u>short-term exposures</u></li></ul>

## ***Overview of Welfare-related chapters***

- Staff approach to visibility substantially changed in response to specific advice and strong recommendation from CASAC
  - New analyses of correlations between urban visibility and PM<sub>2.5</sub> added to Chapter 6, building on discussion of PM-visibility relationships in Chapter 2
  - New recommendations for consideration of a distinct secondary standard for protection of visual air quality presented in Chapter 7
- Ecological section of Chapter 6 revised to address overarching CASAC comments
  - Added discussion of ecological risk assessment and reorganized information to move toward a risk-based framework
  - Added emphasis on “critical loads” approach

## ***Approach to developing staff recommendations on secondary standards***

### ■ Framing questions:

- Adequacy of current standards
  - To what extent does available information demonstrate or suggest that effects occur at current ambient conditions or at levels that would meet the current standards?
  - To what extent does the available information inform judgments as to adversity of any observed or anticipated effects?
  - To what extent are current standards likely to be effective in achieving protection against any identified adverse effects?
- If revision is suggested, what ranges of standards are supportable?
  - Does the available information provide support for considering different indicators or averaging times?
  - What range of levels and forms of alternative standards is supported by the information, and what are the uncertainties and limitations in that information?
  - To what extent would specific levels and forms of alternative standards reduce adverse impacts, and what are the uncertainties in estimated reductions?

## ***Approach to secondary standards . . . protection of visual air quality in urban areas***

- Focus on visual air quality in urban areas reflects:
  - Far less East/West difference in urban visibility than in rural areas
  - Regional Haze Program that focuses on Class I areas
  - Observed urban visibility impairment at levels allowed by current standards
- Correlations between urban PM<sub>2.5</sub> levels and visibility adequate to support use of PM<sub>2.5</sub> indicator for such standards . . . especially when defined for a relatively short (4-8 hours) period of daylight hours (10 am to 6 pm)
  - Recognizes the need for and the availability of continuous monitors
- Recommendations on alternative standard levels informed by:
  - Local/state standards and programs and underlying public perception and attitude surveys
  - Staff observations of photographic representations of visual air quality in a number of urban areas
  - Consideration of background levels
- Recommendations on alternative forms informed by air quality

# PM Health Risk Assessment

Mr. Harvey Richmond  
Office of Air Quality Planning and Standards  
U.S. EPA

Clean Air Scientific Advisory Committee Meeting  
CASAC Particulate Matter Panel  
April 6-7, 2005

## ***PM Risk Assessment . . . Scope and Goals***

- In last PM NAAQS review, a limited risk analysis was conducted
  - Scope included 2 urban counties using PM<sub>10</sub> and PM<sub>2.5</sub> indicators
- In this review, scope has been significantly expanded and methods updated based on CASAC review and consultation
  - Consultation on draft Scoping Plan (July 2001)
    - Expanded scope includes 9 urban areas, additional health endpoints, and PM<sub>2.5</sub>, PM<sub>10-2.5</sub>, and PM<sub>10</sub> indicators
  - Review of PM<sub>2.5</sub> risk methodology (May 23, 2002 Advisory)
    - General methodology judged to be appropriate; comments provided on details of application
  - Consultation on scope and methods issues related to PM<sub>10-2.5</sub> and PM<sub>10</sub> (May 1, 2003)
- Goals for updated risk assessment
  - Provide estimates of the potential magnitude of risks associated with current PM levels and just meeting current and alternative standards
  - Develop better understanding of influence of various inputs and assumptions on risk estimates
  - Gain insights into the nature of the risks associated with exposures to ambient PM

## ***PM Risk Assessment . . . Key Assumptions***

- Risk assessment premised on inferences that the relationships between the specific health endpoints and PM indicators considered in the assessment are likely causal, based on the integrative assessment presented in the PM AQCD
  - Recognized that there are varying degrees of confidence in the inferences related to PM<sub>2.5</sub> and PM<sub>10-2.5</sub> and various endpoints
  - Causal inference with regard to an association between PM<sub>10-2.5</sub> and mortality was judged to be too weak to be included in quantitative risk assessment
- Ambient PM concentrations (as measured at central monitoring stations) are useful surrogates for exposure to ambient PM and are appropriate measures to combine with concentration-response functions from epidemiological studies to estimate risks
  - Recognized that there is more confidence in use of surrogate for PM<sub>2.5</sub> than for PM<sub>10-2.5</sub>



## ***PM Risk Assessment . . . Key Assumptions (cont.)***

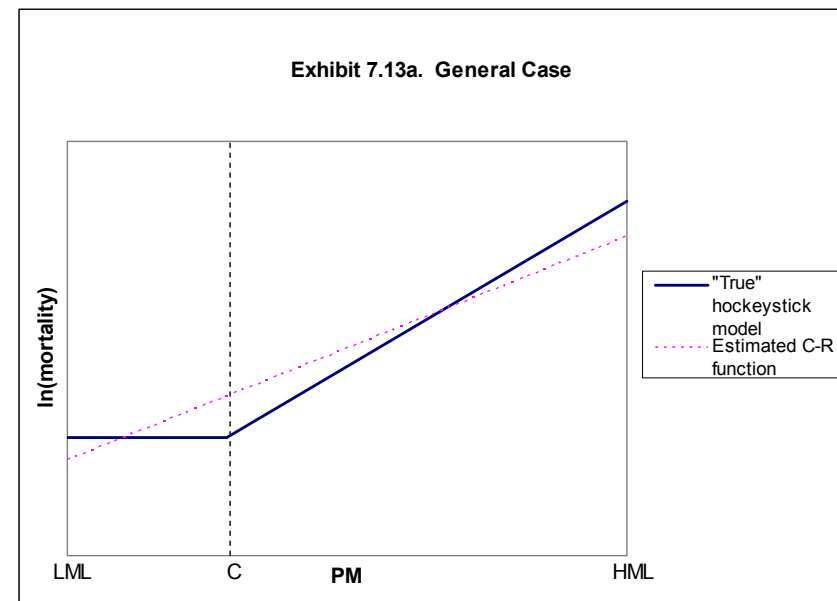
- Concentration-response functions are most appropriately applied within the range of air quality evaluated in the study
  - Did not extrapolate below the lowest measured level in the study (or below estimated policy-relevant background level, whichever is higher)
- Appropriate to use size-based PM mass indicators to estimate risk, while recognizing that components within each size fraction may have differing relative toxicity
  - Applied C-R functions to the same urban area in which they were developed
  - Also applied C-R functions from multi-city studies to urban areas that were included in the study
- Appropriate to use “proportional” rollback method to adjust air
- quality distributions (for concentrations exceeding estimated background levels) to simulate just meeting alternative 24-hour and annual standards
  - Based on . . . ?

## ***PM Risk Assessment . . . simulating “just meeting” standards***

- Simulating PM<sub>2.5</sub> levels for just meeting specified suites of annual and 24-hour standards
  - Air quality adjusted based on 3 years of data (2001-2003)
  - Decreased non-background PM levels on all days by same percentage, with percentage determined by amount needed to roll back values at the **highest community-oriented monitor** to just meet the “controlling standard” for base case analysis
    - e.g., 15 µg/m<sup>3</sup> annual standard is controlling when paired with a 24-hour standard of 65 µg/m<sup>3</sup>, 98<sup>th</sup> percentile
  - Adjustment was applied to single year of PM values (usually 2003 data) at “composite monitor” (values averaged across all monitors reporting concentrations for a given day)
  - Sensitivity analysis in 3 urban areas comparing **spatial averaging** and **highest monitor** approaches to determine compliance
- Simulated PM<sub>10-2.5</sub> levels for just meeting standards (similar approach to above, but only used highest monitor to determine amount of adjustment)
  - Much greater uncertainty about rollback given lack of data to evaluate

# ***PM Risk Assessment . . . hypothetical thresholds***

- **PM<sub>2.5</sub>:**
  - Short-term exposure mortality:  
10, 15, and 20  $\mu\text{g}/\text{m}^3$
  - Long-term exposure mortality:  
10 and 12  $\mu\text{g}/\text{m}^3$
- **PM<sub>10-2.5</sub>:** same as PM<sub>2.5</sub> short-term exposure levels
- **Approach adjusts slope of C-R function above hypothetical threshold**
  - Weighted average of slope above threshold and slope below threshold (zero) = coefficient from study
  - To examine other non-linear functions would require reanalysis of original data which is beyond scope of risk assessment



# ***PM Risk Assessment . . . other sensitivity analyses***

- Alternative model specifications
  - Distributed lag model for PM<sub>2.5</sub> short-term mortality – risk estimates doubled
  - GAM vs. GLM, differing degrees of freedom, single and multi-pollutant models for Los Angeles
    - Decrease, increase, or no change for GLM vs. GAM depending on whether single or multi-pollutant model
    - Wider confidence intervals for GLM vs. GAM-based models
  - Use of different periods of exposure examined for PM<sub>2.5</sub> long-term exposure mortality had moderate impact on risk estimates
- Exceptional event episode
  - Hardly any difference (0-0.1% of short-term exposure total mortality incidence) to small impact (0.2% of long-term exposure total mortality incidence) on PM<sub>2.5</sub> risk estimates from July 2002 Quebec fire episode
- Alternative estimates of PM<sub>2.5</sub> background
  - Small to moderate impact on risk estimates using lower- and upper-end of range of estimated background
  - Use of a varying daily background had very little impact on risk estimates (0.1% in Detroit, no impact in St. Louis)
    - Used new approach (see Langstaff, 2004) to generate year-long series of daily PM<sub>2.5</sub> background values

# Data Analyses in Support of a Revised Secondary PM<sub>2.5</sub> NAAQS Based on Visibility

Mark Schmidt  
U.S. EPA / OAQPS  
April 6, 2005

## ***Estimation of Reconstructed Light Extinction ... Overview***

- SP visibility analyses made considerable use of reconstructed light extinction formula (RE) to estimate RE from:
  - Hourly speciated PM<sub>2.5</sub>
  - Hourly relative humidity
  - Hourly PM<sub>10-2.5</sub>
- RE formula:
$$\text{RE} = \frac{[3 * f(\text{RH}) * \text{PM}_{2.5}\text{Nitrates}] + [3 * f(\text{RH}) * \text{PM}_{2.5}\text{Sulfates}] + [4 * \text{PM}_{2.5}\text{OCM}] + [10 * \text{PM}_{2.5}\text{EC}] + [1 * \text{PM}_{2.5}\text{Crustal}] + [0.6 * \text{PM}_{10-2.5}]}{10}$$
- Estimated RE for every possible site-day-hour for 2003

## ***Estimation of RE ... Input data***

- 24-hour speciation profiles (from EPA urban speciation network) applied to hourly PM<sub>2.5</sub> data.
  - Speciation measurements collocated with or 'nearby' the hourly PM<sub>2.5</sub> monitors. [Previous analyses shows general homogeneity in speciation component profiles within metro areas].
    - Over 25% collocated, 75% are 3 miles apart or less
  - 24-hr profile assumed/determined to be adequate surrogate for same-day hourly PM<sub>2.5</sub> profiles
    - Very limited amount of continuous speciation data
    - Evaluation of pilot continuous instrument study data (Indianapolis, Chicago, Houston, Seattle) found that daily averages of chemical components generally similar to sub-daily averages
- Continuous PM<sub>2.5</sub> mass data from EPA network
  - Urban sites only
  - Utilized almost all AQS methods (TEOM, FDMS, BAM, ...)
    - Some instrument data not FRM-like
    - Effort underway to better qualify continuous AQS data
      - Eventual National and/or regional FRM equivalence

## ***Estimation of RE ... Input data (cont.)***

- Hourly relative humidity (RH) data from nearest National Weather Service (NWS) site
  - NWS RH data generally complete
    - Nearest NWS is 22 miles or closer for 75% of continuous sites
    - Limited amount of collocated (AQS) RH data. But in those instances, collocated hourly AQS RH is fairly well correlated w/ nearby NWS RH.
  - $f(\text{RH})$  from Tang's Curve table
    - RH capped at 95% [7.4  $f(\text{RH})$ ] .... "reflecting lack of accuracy in higher RH values and their disproportionate impact on RE". Also, values above 95 generally synonymous w/ precipitation.
  - Used 'actual'  $f(\text{RH})$  [same-day/hour, nearby], and also 10-year average  $f(\text{RH})$ 
    - 2003 study year comparable to 10-year data
    - 10-year averages "more reflective of long-term humidity patterns".



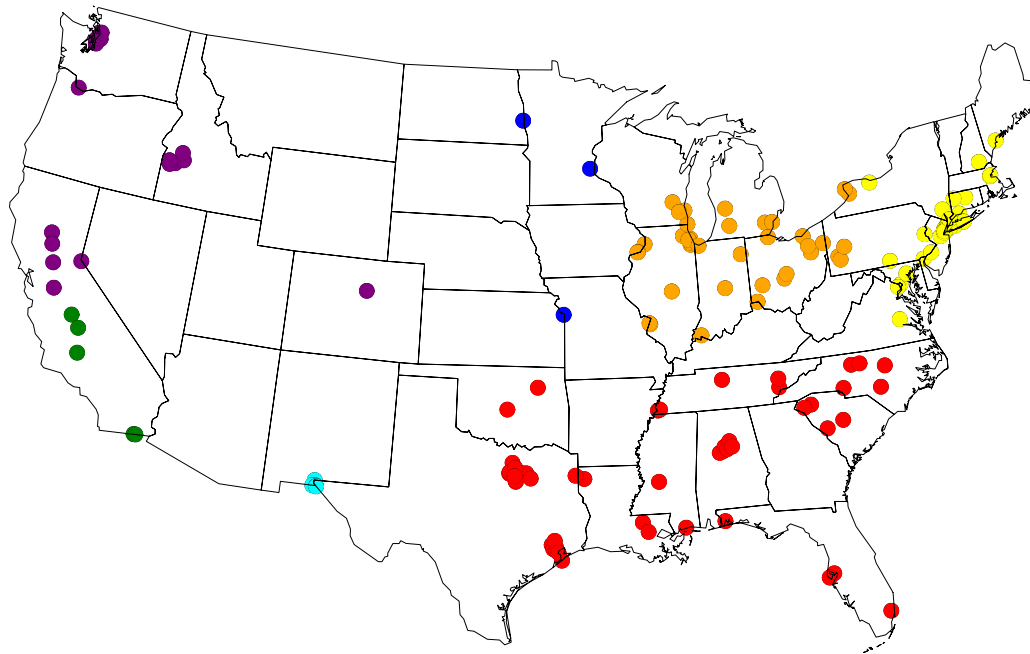
## ***Estimation of RE ... Input data (cont.)***

- Hourly PM<sub>10-2.5</sub> estimated data from collocated continuous PM<sub>10</sub> (by difference method) [ $\sim 13\%$ ] or estimated via regional PM<sub>2.5</sub>/PM<sub>10</sub> ratios.
  - Coarse particles can significantly impact visibility
    - In some areas, PM<sub>10-2.5</sub> levels much higher than PM<sub>2.5</sub>
    - In some areas.... on some days, a future PM<sub>2.5</sub> secondary standard could be met but the area would still have poor visibility because of PM<sub>10-2.5</sub>
  - Limited amount of collocated continuous PM<sub>10</sub> data (i.e., dependence on regional ratios) may cause some over-estimation of PM<sub>2.5</sub>:RE relationship strength in areas subject to PM<sub>10-2.5</sub> episodes

# ***Estimation of RE ... Sites used in analyses***

■ Analyses numbers:

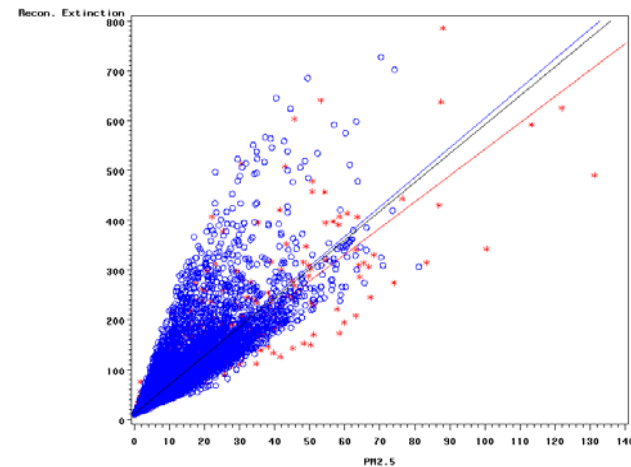
- More than 300K individual observations (site-day-hour)
- Observations in 182 different days of 2003 - limited by speciation
- 161 sites



<b>East</b>		<b>128</b>
Northeast	Yellow	40
Southeast	Red	51
Industrial Midwest	Orange	37
<b>West</b>		<b>33</b>
Upper Midwest	Blue	3
Southwest	Cyan	6
Northwest	Purple	19
Southern California	Green	5

## ***Correlation between RE and PM<sub>2.5</sub>***

- Significant correlation between RE and PM<sub>2.5</sub>
- Example results for 24-hr average:
  - Pearson - using 'actual' f(RH):
    - Overall = 0.86
    - Site level median = 0.83
  - Pearson –using '10-yr avg. f(RH)'
    - Overall = 0.95
    - Site level median = 0.97
- Example results for 12-4 p.m.:
  - Pearson - using 'actual' f(RH):
    - Overall = 0.82
    - Site level median = 0.82
  - Pearson –using '10-yr avg. f(RH)'
    - Overall = 0.96
    - Site level median = 0.98

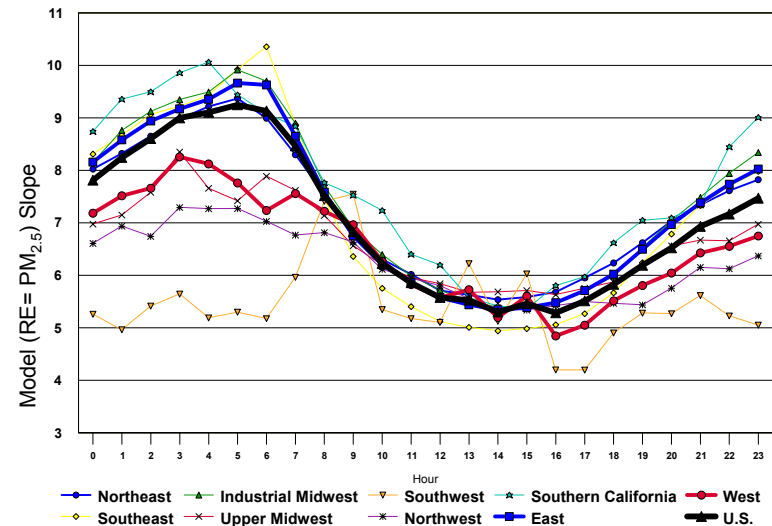


**Relationship between RE and 12 p.m. – 4 p.m. average PM<sub>2.5</sub>, 2003. RE computed using actual  $f(RH)$ .**

*PM<sub>2.5</sub> judged to be adequate indicator for visibility*

# Focus on sub-daily correlations

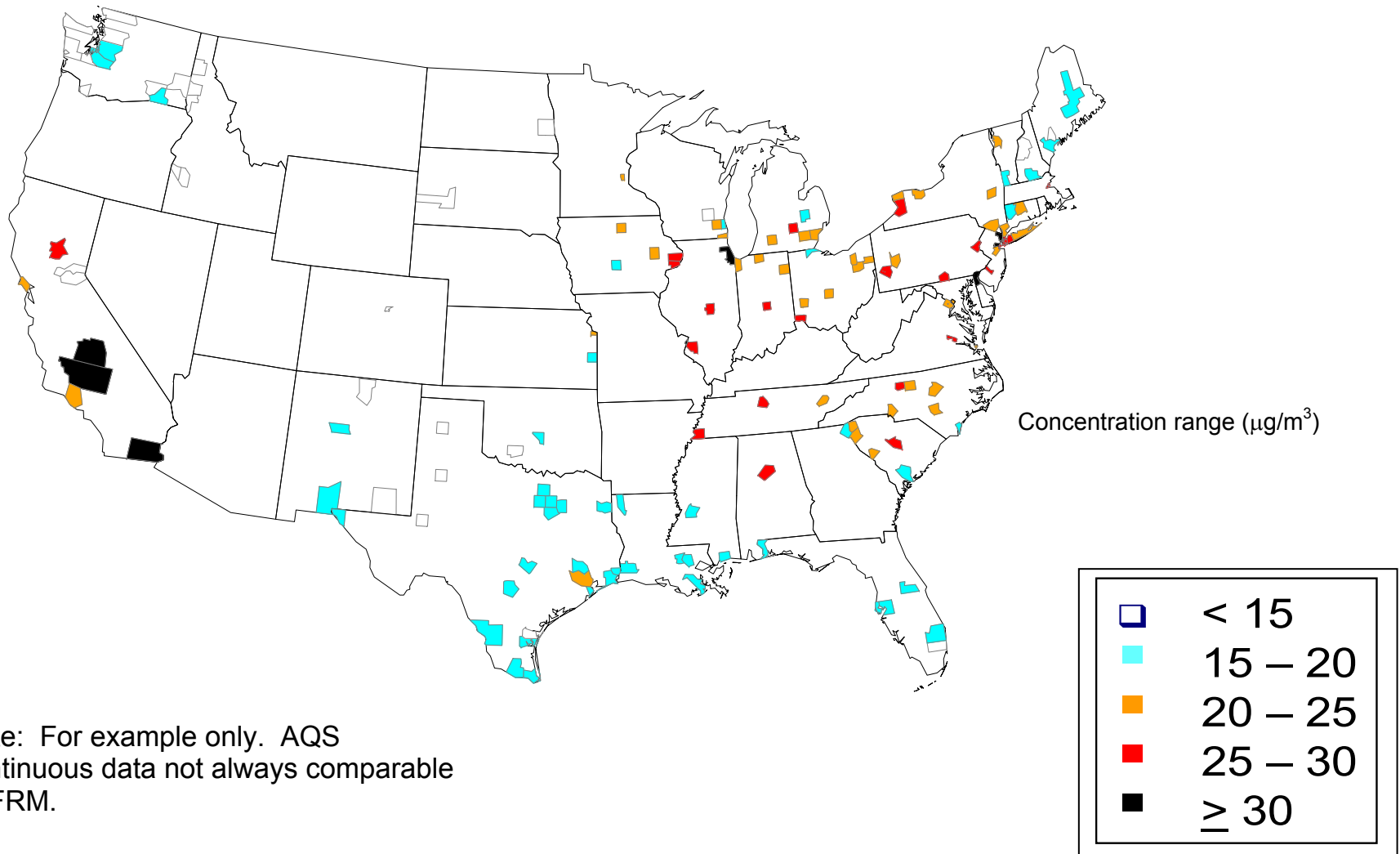
- RH effects minimized during daylight hours (lower model slope)
  - Slope more closely approximates dry particle extinction efficiency (i.e. more closely tied to emissions)
- RE:PM<sub>2.5</sub> relationship more similar across regions during daytime
  - More national consistency in potential visibility improvements (benefits) from emission reductions
- Correlation comparably high during daylight hours
- Other considerations:
  - Importance of visibility in urban areas during daylight hours
  - Sub-daily timeframe would provide



Model slope for relationship between reconstructed light extinction (RE) and hourly PM<sub>2.5</sub> (increase in RE due to incremental increase in PM<sub>2.5</sub>), 2003. RE computed using 10-year average  $f(RH)$ .

*Daylight time periods more appropriate timeframe than 24-hr*

***Estimated county-level max 90<sup>th</sup> percentile 4-hr  
(12-4 p.m.) average  $PM_{2.5}$  concentration, 2001-2003***



# Update on Coarse-Fraction Particulate Matter (PM<sub>c</sub>) Monitoring and Relationship to National Ambient Air Quality Standards (NAAQS)

Presentation to Clean Air Scientific Advisory Committee  
4/6/2005

Tim Hanley – EPA Office of Air Quality Planning and Standards

Represents on-going work by EPA-ORD and EPA-OAQPS

# PMc Methods Research Update

- Multi-city field study of commercially available PMc technologies completed and reviewed by CASAC Ambient Air Monitoring and Methods (AAMM) Technical Subcommittee last Summer
  - Study methods included:
    - Dichot and FRM difference method integrated samplers
    - Coarse TEOM and Beta Gauge continuous methods
    - Aerodynamic Particle Sizer (APS) for size distribution
- Major take home messages of field study and subcommittee review:
  - Field study was able to capture wide range of PMc conditions
  - Difference method appears to be strong candidate for use as the method of comparison in a performance based approach for approval of other methods
  - Good precision and correlation between methods
  - High sample completeness
  - No measured results with negative numbers
  - Some biases exist between methods

## PMc Methods Research Update - Continued

- Results from completed tests were provided to instrument manufacturers. Improvements in sampler designs were performed by many of the instrument companies.
- EPA/ORD is preparing for another field study in Phoenix, AZ in May of 2005. A total of 28 samplers will be operated.
  - Filter methods expected in study include:
    - Difference method using FRMs
    - Sequential and single channel Dichots
    - BGI Omni saturation Monitors (also a difference method)
  - Continuous methods expected in study include:
    - R&P Coarse TEOM, R&P Dichot TEOM
    - Kimoto Dichot Beta Gauge
    - TSI APS
    - Grimm Optical sampler
- Results of field study will be reviewed in scheduled consultation with CASAC AAMM subcommittee - expected late summer 2005.



# Development of Data Quality Objectives

- The Data Quality Objective (DQO) process is being used to identify the acceptable level of uncertainty for:
  - Operation of an agency's PMc monitoring network
  - Approval criteria for reference and equivalent PMc methods
- How are these DQOs being developed?
  - Using DQO Tool developed during implementation of PM2.5 network
    - Use ranges and forms of potential PMc standard identified in PM staff paper as inputs
    - Use method precision and bias data from EPA-ORD field study.
    - Use conservative estimates for sample population
    - Calculate uncertainty ranges and evaluate inputs that are more or less sensitive to changing the uncertainty range
      - Due to high variability in sample population, a daily sample frequency appears very important in optimizing the uncertainty range
  - Approval criteria for PMc reference and equivalent methods expected to follow similar process used in recent development of new draft PM2.5 equivalency criteria for continuous methods
    - Consider total bias with flexibility between slope and intercept
    - Use sample population to define minimum acceptable correlation
- DQO Tool is being updated for:
  - Spatial variability component
  - Applicable metrics to support approval of methods:
    - Additive (intercept) and multiplicative bias (slope)
    - Correlation

# PMc Network Design Considerations

- Design should consider multiple objectives
- Design is challenged by high degree of spatial and temporal variation in coarse particle concentrations
  - Emphasis on continuous PMc monitoring technologies will partially compensate for high spatial and temporal variation
- Working to tie scale of representation, monitoring objective, and location setting recommendations in network with data utilized in health studies cited in 2<sup>nd</sup> draft of PM Staff Paper.
- PMc network would likely consist of:
  - Some existing PM10 sites
  - Representative urban and rural (away from any local sources) multi-pollutant sites
  - New locations, where appropriate

## Appendix D – List of Public Speakers

### List of Public Speakers

**U.S. Environmental Protection Agency  
Clean Air Scientific Advisory Committee (CASAC)  
CASAC Particulate Matter (PM) Review Panel**

### **Peer Review of EPA's 2<sup>nd</sup> Draft Particulate Matter (PM) Staff Paper and 2<sup>nd</sup> Draft PM Risk Assessment**

**Public Meeting ❖ April 6-7, 2005**

**Marriott Durham Civic Center Hotel  
210 Foster Street, Durham North Carolina, 27701**

#	Speaker's Name	Organizational Affiliation(s)	Organization(s) Represented (i.e., comments offered on behalf of)
1	Dr. Gina Solomon (M.D.)	Natural Resources Defense Council (NRDC)	same
2	Dr. Michael Lipsett (M.D.)*	University of California, San Francisco (UCSF) School of Medicine	none (speaking on own behalf)
3	Dr. Mark Frampton (M.D.)	University of Rochester [NY] Medical Center	American Thoracic Society (ATS)
4	Mr. Philip Johnson	Northeast States for Coordinated Air Use Management (NESCAUM)	same
5	Dr. Allen Lefohn	A.S.L. & Associates	same
6	Mr. Kurt Blase	O'Connor & Hannan L.L.P.	Coalition for Coarse Particle Regulation
7	Mr. Greg Shaefer	Arch Coal	Coalition for Coarse Particle Regulation
8	Ms. Martha Keating	Clean Air Task Force (CATF)	same
9	Dr. Linda Smith*	California Environmental Protection Agency, Air Resources Board (CARB)	same
10	Dr. Bart Ostro*	California Office of Environmental Health Hazard Assessment (OEHHA)	same
11	Dr. Anne Smith	Charles River Associates, Inc.	Utility Air Regulatory Group (UARG)
12	Ms. Deborah Shprentz	Consultant	American Lung Association (ALA)
13	Dr. John Balbus (M.D.)*	Environmental Defense; and American Public Health Assoc. (APHA) (Chair, APHA Environment section)	APHA
14	Dr. Ron Wyzga	Electric Power Research Institute (EPRI)	same
15	Mr. Kyle Kinner*	Physicians for Social Responsibility (PSR)	same
16	Dr. George Lucier	Environmental Defense	same

#	Speaker's Name	Organizational Affiliation(s)	Organization(s) Represented (i.e., comments offered on behalf of)
17	Dr. Ron Wyzga (for Dr. Naresh Kumar)	EPRI	Southern Company
18	Dr. Rose Marie Robertson (M.D.)*	American Heart Association (AHA)	same
19	Ms. Tamara Thies	National Cattlemen's Beef Association (NCBA)	same
20	Mr. Robert Connery	Holland & Hart LLP	NCBA
21	Mr. Jon Heuss	Air Improvement Resource, Inc. (AIR)	same
22	Dr. Suresh Moolgavkar (M.D.)*	Sciences International, Inc.	PM Fine Coalition
23	Dr. George Thurston*	New York University (NYU) School of Medicine	none (speaking on own behalf)
24	Dr. Judith Voynow (M.D.)*	Duke University Medical Center	none (speaking on own behalf)
25	Mr. Casimer Andary	Alliance of Automobile Manufacturers (AAM)	same
26	Dr. Kenny Crump	ENVIRON Health Sciences Institute	same
27	Mr. Joe Suchecki	Engine Manufacturers Association (EMA)	same
28	Dr. Katherine Shea (M.D.)**	University of North Carolina (UNC), Chapel Hill	American Academy of Pediatrics (AAP)
29	Dr. Ira Tager (M.D.)* **	School of Public Health, University of California, Berkeley	none (speaking on own behalf)
30	Dr. Bonnie New (M.D.)* **	Health Professionals for Clean Air	same

\*Note: Will present oral comments via teleconference (phone) line

\*\*Note: Will present oral comments on Thursday morning, April 7

Note: Dr. Voynow, Mr. Andary and Dr. Tager were scheduled but did not actually make public comments.